



EUROPEAN COMMISSION

Bruxelles, 21.6.2013
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COMMISSION IMPLEMENTING DECISION

of 21.6.2013

granting marketing authorisation under Regulation (EC) No 726/2004 of the European Parliament and of the Council for "Xtandi - enzalutamide", a medicinal product for human use

(Text with EEA relevance)

(ONLY THE DUTCH TEXT IS AUTHENTIC)

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THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency¹, and in particular Article 10(2) thereof,

Having regard to the application submitted by Astellas Pharma Europe B.V., on 15 August 2012, under Article 4(1) of Regulation (EC) No 726/2004,

Having regard to the opinion of the European Medicines Agency, formulated on 25 April 2013 by the Committee for Medicinal Products for Human Use,

Whereas:

- (1) The medicinal product "Xtandi - enzalutamide" complies with the requirements set out in Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use².
- (2) It is therefore appropriate to authorise its placing on the market.
- (3) The Committee for Medicinal Products for Human Use considered that enzalutamide is a new active substance.
- (4) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on Medicinal Products for Human Use,

HAS ADOPTED THIS DECISION:

Article 1

The marketing authorisation provided for in Article 3 of Regulation (EC) No 726/2004 is granted for the medicinal product "Xtandi - enzalutamide", the characteristics of which

¹ OJ L 136, 30.4.2004, p. 1.

² OJ L 311, 28.11.2001, p. 67.

are summarised in Annex I to this Decision. "Xtandi - enzalutamide" shall be registered in the Community register of medicinal products under number EU/1/13/846.

Article 2

The marketing authorisation concerning the medicinal product referred to in Article 1 shall be subject to compliance with the conditions set out in Annex II and, in particular, with those relating to manufacture and importation, control and issue.

Article 3

The labelling and package leaflet concerning the medicinal product referred to in Article 1 shall comply with the conditions set out in Annex III.

Article 4

The period of validity of the authorisation shall be five years from the date of notification of this Decision.

Article 5

This Decision is addressed to Astellas Pharma Europe B.V., Sylviusweg 62, NL-2333 BE Leiden, Nederland.

Done at Brussels, 21.6.2013.

For the Commission
Paola TESTORI COGGI
Director-General